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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,544	03/19/2002	Laurent Di Costanzo	C1190/20009	7903

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EXAMINER

DICKINSON, PAUL W

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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07/14/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No. 09/914,544	Applicant(s) COSTANZO ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Examiner for this Application is now Paul Dickinson. The Examiner's correspondence information is provided at the end of this action.

Applicant's arguments, filed 5/3/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 21-41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 6391337) in view of Schmitz et al (US 6079968) and Valentine (US 4684534). Claims 31 and 42-47 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter et al (US 6391337) in view of Smitz et al (US 6079968).

Applicant amends Claims 21, 31 and 45 to specify that the active substance comprised in the tablet is "in a form of coated microcrystals or coated microgranules." Applicant argues that in the tablet taught by Hunter et al, the active substance acetaminophen is in granular form and is not coated. Further, Hunter et al does not disclose or suggest a compressible tablet comprising an active principle that is enveloped by a coating nor is "in a form of coated microcrystals or coated microgranules."

Applicants arguments have been fully considered but are not found persuasive. Hunter et al teaches an embodiment wherein the acetaminophen granules are coated (see col 13, lines 54-58). In this embodiment, silicon dioxide is added to the acetaminophen granules and direct compression vehicle (i.e. microcrystalline cellulose granules) and subjected to shear mixing. The acetaminophen granule size of 50-500 microns is chosen such that the granules will not break apart under the high shear mixing conditions (see col 7, lines 45-67). Hunter et al teaches that the effect of mixing the silicon dioxide with the direct compression vehicle is that the vehicle is partially coated with the silicon dioxide (see col 9, lines 9-21). In the embodiment wherein silicon dioxide is added to the acetaminophen granules and subsequently mixed, it is reasonable that at least a portion of the granules are at least partially coated with the silicon dioxide.

The rejection of Claims 21-41 under 35 U.S.C. 103(a) as being unpatentable over Hunter et al in view of Schmitz et al and Valentine is maintained. The rejection of Claims 31 and 42-47 under 35 U.S.C. 103(a) as being unpatentable over Hunter et al in view of Schmitz et al is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent Claim 21 requires the lubricating agent to be both distributed on the tablet surface and mixed with the interior contents of the tablet. Dependent Claim 41 requires all of the lubricating agent to be distributed on the tablet surface. It is unclear how this limitation could fall under the scope of the independent claim, since none of the lubricating agent would be mixed with the interior contents of the tablet.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-25, 29-30, 33, 35 and 41 are rejected under 35 U.S.C 102(b) as being anticipated by US 5725880 ('880). '880 discloses a plain tablet (a directly compressible tablet) comprising a dry mixture of a 5-Aminosalicylic acid (an active substance) and excipients including calcium carboxymethylcellulose (a disintegrating agent), calcium citrate (a soluble agent with binding properties), and magnesium stearate (a lubricating agent) in powder form, wherein more than half of the magnesium stearate is distributed on the tablet surface and wherein the active substance is in a form of coated microgranules (see Example 3). There is 1.06 mg of magnesium stearate in the plain

Art Unit: 1618

tablet (calculated from $70 \text{ mg} \times (10/(530 + 120 + 10))$) and 20 mg of magnesium stearate on the surface of the tablet (calculated from $200 \text{ mg} \times (1/(8 + 1 + 1))$). Calcium stearate (a lubricant) is also present on the surface of the plain tablet, and not in the interior, and this satisfies a possible embodiment of Claim 41 (see ***Claim Rejections - 35 USC § 112***).

Although '880 does not disclose all the characteristics and properties of the composition disclosed in the present claims, based on the substantially identical process using identical components, the Examiner has a reasonable basis to believe that the properties claimed in the present invention are inherent in the tablet disclosed by the reference. Because the PTO has no means to conduct analytical experiments, the burden of proof is shifted to the Applicant to prove that the properties are not inherent. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).” MPEP 2112, I.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

July 3, 2008